Supreme Court, U.S.
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No. 01-188

IN THE

Supreme Court of the United States

PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA,

Petitioner,

v.

KEVIN CONCANNON, COMMISSIONER, MAINE DEPARTMENT OF HUMAN SERVICES, AND G. STEVEN ROWE, ATTORNEY GENERAL OF MAINE,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the First Circuit

REPLY TO BRIEF IN OPPOSITION

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REPLY TO BRIEF IN OPPOSITION

Maine proposes to compel out-of-state drug manufacturers that sell their products to wholesalers outside Maine to pay the state each time their products are sold by retailers to Maine residents. To secure compliance, Maine threatens those manufacturers with restrictions on Medicaid patient access to (and hence sales of) the manufacturers' drugs if they do not pay these subsidies for non-Medicaid populations in Maine. The constitutional and statutory defects of the "Maine Rx" program are ripe for review by the Court, and review at this time is of national importance as states around the country consider similar programs of their own.

I. The Maine Act Is Facially Defective and Its Immediate Consequences Warrant Review at This Time.

Contrary to Maine's argument that review by the Court is premature, the issues in this facial challenge are fully joined and ready for this Court's consideration. No further factual development is required. The Maine Rx program is not voluntary and its effects are not hypothetical: it regulates the terms of out-of-state prescription drug sales, in violation of the Commerce Clause, and its enforcement tool—imposing obstacles to drug coverage for Medicaid beneficiaries, in order to secure price discounts for individuals outside Medicaid—necessarily interferes with the federal Medicaid program.

A. The Maine Rx Program Is Mandatory.

Maine suggests that Maine Rx is merely a "voluntary" subsidy program for Maine's citizens in which out-of-state drug manufacturers may "elect[] to participate," Opp. 2, 3, and that this Court's attention would be premature because

the terms of manufacturers' participation have yet to be "negotiated."

Maine's characterization of the Act is inaccurate. Having declared manufacturers' prices to be "excessive" (App. 101), the Act by its terms requires manufacturers to enter into rebate agreements, and penalizes them severely if they refuse to pay the rebates sought by the state. Simply put, there is nothing to "negotiate." The Maine Rx program is not hortatory but a direct exercise of the state's regulatory authority. To illustrate:

- The Act directs that manufacturers "shall *enter into*" rebate agreements with the state. 22 Me. Rev. Stat. Ann. § 2681(3) (emphasis added). The Act does not invite manufacturers to negotiate rebate agreements; it requires manufacturers to *sign* them.
- The Act candidly speaks of the "rebate *required* from the manufacturer," and explains, for example, that a Maine Rx agreement "*must require* the manufacturer to make [a] rebate payment[] to the State" on a regular schedule. 22 Me. Rev. Stat. Ann. § 2681(3),(4) (emphasis added).
- Any manufacturer that refuses to enter into a rebate agreement faces the sanction of "prior authorization" requirements for their drugs. 22 Me. Rev. Stat. Ann. § 2681(7). The Court of Appeals itself acknowledged that participation in the Maine Rx program is "coerce[d]" by the economic "'hammer' or 'force'" of prior authorization. App. 16-17.

Maine Rx rebates are "voluntary," Opp. 3, only in the sense that manufacturers can disregard the direct statutory command to enter into rebate agreements if they are willing to suffer the serious penalty of prior authorization. By this reasoning, no legislative command is ever compulsory, because all legislative commands—from the obligation to pay taxes to the prohibition on assault—may be ignored as

long as the offender is willing to suffer the consequences. But the ability of a regulated entity to disregard the law does not change the Act from a regulation to an invitation. It does not immunize the Maine Rx program from constitutional and statutory challenges.

B. Petitioner's Claims Are Ripe for Review.

There is nothing interlocutory about the First Circuit's ruling on PhRMA's facial challenges to Maine's statute under the Supremacy Clause or the Commerce Clause. The First Circuit's ruling that Maine may restrict Medicaid patient access to the drugs of manufacturers who do not pay for Maine Rx is final. So too is its ruling that Maine may require out-of-state manufacturers who do not sell their drugs to Maine consumers to subsidize discounts for those consumers. Moreover, no further factual development is needed to test the validity of these rulings.

The imposition of prior authorization requirements—however they are implemented—will necessarily impede the flow of Medicaid benefits to Medicaid recipients. The First Circuit suggested that medical harm to Medicaid patients must be shown in order to establish that Maine Rx interferes with the Medicaid program, and that evidence of such harm should be presented in an "as applied" challenge. App. 16. That holding was mistaken. The courts need not await actual harm to Medicaid patients before addressing PhRMA's preemption challenge. PhRMA has demonstrated that the Act will necessarily constrain the benefits provided for by Congress, for purposes unrelated to Medicaid. That showing is sufficient to justify this Court's review of the Act.

Because of the state's efforts to raise funds for the non-Medicaid Maine Rx program, drugs that previously were covered routinely by Medicaid and available to Medicaid patients and doctors without hindrance will now be more difficult to obtain. Although the state may ultimately

approve a given prescription, the doctor will first have to undertake the burden of making a request to state Medicaid officials and providing written documentation to justify the need for that prescription, for reasons having nothing to do with the safety or economics of the Medicaid program itself. In many cases, the doctor may simply avoid the procedural burden and prescribe second-choice medications instead.

Thus while Respondents might dispute whether all noncompliant manufacturers' drugs will be subject to prior authorization, and whether Medicaid patients ultimately will be refused medically necessary drugs, Opp. 4, 8; App. 14-16, they cannot contest that the imposition of the prior authorization procedure in and of itself restricts Medicaid patient and doctor access to the listed drugs, and does so for purposes unrelated to Medicaid. In the words of the district court, while "the parties disagree on the severity of the obstacle," prior authorization "*is* an obstacle." App. 68 (emphasis added). The very fact that the Act relies on the threat of prior authorization to force manufacturers to pay the required rebates is compelling evidence of its effects.

Accordingly, no further factual development or "as applied" litigation is necessary and PhRMA's facial claims are ripe for review. The Court should disregard any suggestions for delay.

II. The Maine Act Is Preempted by the Federal Medicaid Statute.

A. PhRMA Has Standing To Challenge Maine's Interference with the Federal Medicaid Program.

Maine does not dispute that PhRMA meets Article III standing requirements for its Commerce and Supremacy Clause challenges: PhRMA members are immediately threatened with injury that is both directly attributable to the Maine Rx program and addressable by the courts. *See*

Assoc. Gen. Contractors v. Jacksonville, 508 U.S. 656, 663-64 (1993).

However, Maine renews its claim, raised for the first time on appeal,[1] that PhRMA lacks prudential standing to advance its preemption challenge to the Maine Rx program, suggesting that PhRMA's members are not within the "zone of interests" of the Medicaid statute. Opp. 13-14. The First Circuit rejected that argument, explaining—consistent with other Courts of Appeals—that PhRMA's prudential standing is grounded in the Supremacy Clause. App. 6-8, citing *St. Thomas-St. John Hotel & Tourism Ass'n. v. Virgin Islands*, 218 F.3d 232, 241 (3d Cir. 2000) (state law can be "preempted by federal law even when the federal law secures no individual substantive rights for the party arguing preemption"). PhRMA is not attacking the Medicaid statute or its implementation, and need not be within that statute's "zone of interests." PhRMA members are undeniably regulated by the statute that it does challenge—namely, the Maine Act. A party regulated by a state statute that conflicts with a governing federal law has a direct cause of action under the Supremacy Clause. *See, e.g.*, *City of Burbank v. Lockheed Air Terminal Inc.*, 411 U.S. 624 (1973) (considering a preemption claim without reference to any substantive federal rights or private right of action on the part of the plaintiff).[2]

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[1] Maine should be deemed to have waived any prudential standing objection, as PhRMA argued below. *See Pershing Park Villas Homeowners Assoc. v. United Pacific Ins. Co.*, 219 F.3d 895, 899 (9th Cir. 2000); *Lindley v. Sullivan*, 889 F.2d 124, 129 (7th Cir. 1989); *but see Community First Bank v. National Credit Union Admin.*, 41 F.3d 1050, 1053 (6th Cir. 1995).

[2] Maine also suggests that PhRMA's right to advance a Supremacy Clause claim depends on whether it claims violations of federal rights enforceable under 42 U.S.C. § 1983. Opp. 14-15. No such link exists; courts routinely entertain preemption

Even if prudential standing under the federal Medicaid statute were an additional requirement for a preemption challenge, PhRMA meets that test. PhRMA's members participate in the Medicaid drug assistance program, the terms of which (such as the calculation of rebate amounts and obligations to supply data) directly regulate manufacturers. *See generally* App. 73-84.

More important, the Medicaid statute also protects manufacturers by setting forth the terms of the *quid pro quo* of their participation in the Medicaid drug program: manufacturers pay rebates to Medicaid, in exchange for which their drugs are made available to Medicaid patients for purchase with Medicaid funds. The Medicaid drug coverage obligation is subject to only limited exceptions. *See* App. 79-81. By conditioning access to Medicaid coverage on Maine Rx payments, Maine has unilaterally reduced the "benefit" of the manufacturers' Medicaid bargain. The terms of that delicately balanced bargain were set out by Congress in the Medicaid statute,[3] and both

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claims directly under the Supremacy Clause. *See, e.g., Western Air Lines, Inc. v. Port Auth. of N.Y. and N.J.*, 817 F.2d 222, 225-26 (2d Cir. 1987) (considering Supremacy Clause claim absent a direct right of action under federal statute); *Maryland Pest Control Ass'n v. Montgomery County*, 884 F.2d 160, 162-63 (4th Cir. 1989) (per curiam) (plaintiffs prevailed on Supremacy Clause claim but lacked claim under § 1983 to support § 1988 attorneys fees) (citing other cases), *cert. denied*, 494 U.S. 1056 (1990); *Pirolo v. City of Clearwater*, 711 F.2d 1006, 1010 (11th Cir. 1983) (affirming invalidation of regulations under Supremacy Clause while also affirming dismissal of § 1983 claim).

[3] *See, e.g., Medicare and Medicaid Budget Reconciliation: Hearings before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 103d Cong., 1st Sess. 453 (1993) (Rep. Waxman, describing genesis of Medicaid drug rebate program's "government-industry compact").

manufacturers and the states are protected by them for prudential standing purposes.

B. Express Preemption Is Not Required.

Maine suggests that because its use of Medicaid regulatory authority here is not expressly prohibited by the terms of the federal Medicaid statute, it is not preempted by the federal law. Opp. 9, 13. That suggestion, however, misapprehends the law of conflict preemption. It is axiomatic that federal and state laws can conflict even in the absence of a direct federal prohibition on a given state activity. Indeed, even where a federal statute and a state statute are directed to the same goals,[4] the state measure can interfere impermissibly with Congress's objectives and the means it chose to implement them in the federal law. *See, e.g., Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 379-80 (2000). Maine's threat to hold Congress's Medicaid beneficiaries hostage to efforts to subsidize state citizens who are ineligible for Medicaid necessarily interferes with Congress's goals in the federal Medicaid statute. The Act is therefore preempted.

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[4] In fact, Medicaid and the Maine Act do not serve the same objectives. Congress enacted Medicaid to provide medical services to specific categories of needy persons. The Maine Rx program is open to all residents of the state, regardless of income, age, or access to health insurance. Nor is the state's alleged "Medicaid purpose" of Maine Rx (keeping non-Medicaid individuals from becoming so poor as to qualify for Medicaid) a viable defense. The same purpose could be articulated for all state public assistance programs, yet Congress surely did not intend Medicaid regulatory authority to be employed to raise funds for them.

C. The Ruling Below Conflicts with the D.C. Circuit's Ruling in *Thompson*.

Maine obscures the simple logical conflict between the First Circuit's interpretation of the Medicaid statute here and that of the D.C. Circuit in *PhRMA v. Thompson*, 251 F.3d 219 (D.C. Cir. 2001). The First Circuit would allow Maine to leverage its authority in administering the federal Medicaid program to secure drug price rebates for non-Medicaid patients. In *Thompson*, the D.C. Circuit refused to permit Vermont to do so, even under the auspices of the U.S. Department of Health and Human Services. As the D.C. Circuit explained, Congress in the Medicaid statute has not authorized HHS to permit states to "require pharmaceutical manufacturers to provide substantial discounts to individuals not otherwise covered by state Medicaid programs." *Id.* at 226. The two courts have thus reached opposite conclusions as to whether the Medicaid statute can be stretched to provide states with leverage to make manufacturers finance benefits for non-Medicaid populations. Particularly because this conflict presents an issue of such national currency and importance, this Court's attention is warranted.

III. The Maine Act Violates the Commerce Clause.

It is undisputed that a state may not regulate beyond its borders, even if the regulated activity has some ultimate effect in the state. Maine itself acknowledges that under the Commerce Clause it could not tax the sale of computer chips in California or the sale of oil in Texas simply because those products are later sold in Maine, Opp. 20 n.10 responding to Pet. 17 n.6. But it offers no explanation for why the same is not true of prescription drugs sold in New Jersey or other states.

Maine echoes the First Circuit's erroneous proposition that Maine Rx should be understood as an in-state regulation

with only incidental out-of-state effects. While the trigger for a Maine Rx rebate payment is an in-state pharmacy sale, the manufacturer from whom the "rebate" is demanded does not make that in-state sale. In virtually all cases, it makes *no* sale in Maine that leads to that pharmacy counter. Hence, the only transaction that Maine could be regulating when it demands a rebate from a manufacturer is the manufacturer's out-of-state wholesale sale. This constitutes hands-on regulation, tantamount to taxation, of the manufacturer's out-of-state sales.

Maine also urges that the Commerce Clause is inapposite because the Act is not a protectionist statute. That proposition misreads this Court's Commerce Clause precedents, which are not solely directed to foreclosing protectionist state legislation. The Commerce Clause also imposes basic territorial limits on state authority. This Court's opinions barring extraterritorial overreaching—such as *Baldwin v. G.A.F. Seelig*, 294 U.S. 511 (1935), *Healy v. The Beer Institute*, 491 U.S. 324 (1989), and *Brown-Forman Distillers Corp. v. New York State Liquor Auth.*, 476 U.S. 573 (1986)—cannot be read as exclusively concerned about protectionism, as Maine suggests (Opp. 19).[5] Courts routinely apply the territorial doctrine of those cases. *See, e.g.*, *Dean Foods Co. v. Brancel*, 187 F.3d 609, 614-15 (7th Cir. 1999).

Even if a protectionist purpose or effect were required, the Maine Act would qualify, contrary to the state's contentions (Opp. 21-22). Maine has protected its own consumers at the expense of those outside the state. The Maine Rx program ties the amount of the rebate not to any

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[5] For example, the Court's opinion in *Healy* describes the Connecticut price affirmation statute's discriminatory aspects as a "second" Commerce Clause offense, as distinguished from its "extraterritorial reach." 491 U.S. at 340.

aspect of the in-state pharmacy sale, but to federal program rebates and prices, which in turn are based on prices around the country. That price tying will deprive consumers in the national marketplace of their competitive advantages—the very same market-distorting protectionist effects that troubled the Court in *Brown-Forman* and *Healy*. Every time a manufacturer sets a price that is the basis of the Medicaid or Federal Supply Schedule price, it will have to take into account its effect on rebates owed to Maine. The manufacturer can no longer price in the national market solely according to competitive conditions there—it must factor Maine Rx into the equation as well. This effect will be compounded at a rapid rate as other states enact "State Rx" laws, spiraling into pricing gridlock.[6]

Finally, Maine continues to assert that it is merely a market participant, Opp. 19 n.9, despite the First Circuit's decisive rejection of that argument below, App. 20. Maine is *not* a market participant—it does not buy Maine Rx drugs. On the contrary, the Act regulates manufacturers by requiring them to provide discounts to private purchasers. Maine may not leverage regulatory and market power from the Medicaid market into the Maine Rx market. *See* App. 61-64, citing *South Central Timber Dev. Inc. v. Wunnicke*, 467 U.S. 82, 96-98 (1984) (plurality op.).

CONCLUSION

For the foregoing reasons and those set out in the Petition, the Petition should be granted.

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[6] That other states may have deferred enacting copycat laws during the pendency of this suit does not diminish the urgency or national importance of the case, as Maine suggests (Opp. 25). Some 40 states have already considered price-related bills in 2001, including many modeled on Maine Rx. Such efforts are sure to be renewed in their next legislative sessions.

Respectfully submitted,

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